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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,000	03/27/2001	Fang Lu		1998

7590 05/04/2004

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,000	LU ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 March 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Objections

1. Claims 1 and 6 are objected to because of the following informalities:

a) Claim 1: "Providing" and "Means" should not begin with capital "P" and "M", respectively; and

b) Claim 6: "Providing," "Applying," "Monitoring," and "Correlating" should not begin with capital "P", "A", "M", and "C", respectively.

2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 1: the statutory class of invention is indefinite. The preamble recites method of using limitations, but the body of the claim, which describes the improvement over the process of the preamble, lists structural limitations;

b) Claims 4 and 7: what is the intended meaning of "perm-selective"?

c) Claim 8, line 3: -- second -- should be inserted between "said" and "insulation";

d) Claim 8, line 3: "insulation" should be -- insulating --; and

e) Claim 9 appears to be inconsistent with claim 7. Claim 9 requires a filter membrane, but Claim 7 requires the working electrode to be devoid of a perm-selective membrane.

5. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by the JPO computer translation of Tadahisa (JP 09-264870), hereafter "Tadahisa."

Addressing claim 1, Tadahisa teaches a system for direct electrochemical measurement of enzymatically liberated hydrogen peroxide formed incident to the biocatalytic conversion of an analyte of interest (paragraph [0018] of the "Detailed Description"), wherein the analyte is (a)

initially exposed to an oxidase specific for biocatalytic conversion of the analyte into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description"), and (b) the hydrogen peroxide is reduced, under electrochemical conditions, so as to generate an electrical signal indicative of the presence and/or concentration of the analyte in the sample (paragraph [0018] of the "Detailed Description"), wherein the improvement comprises

a) providing a biosensor assembly comprising a working electrode (25) and a counter electrode (24), the working electrode having an effective amount of enzymatically active oxidase specific for biocatalytic conversion of an analyte of interest into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description"), and a metal doped carbon composition specific for catalytic reduction of enzymatically-liberated hydrogen peroxide (paragraphs [0006] and [0018] of the "Detailed Description");

b) means for applying an electrical potential to the electrodes, wherein the potential is within a range of from about +0.4 V of about –0.3 (paragraph [0018] of the "Detailed Description". Also note the embodiment in paragraph [0018] of the "Detailed Description" in which 0.7 V is used);

c) means for monitoring, under electrochemical conditions, the rate of catalytic reduction of enzymatically –liberated hydrogen peroxide by the working electrode (implied by paragraph [0018] of the "Detailed Description, " which teaches correlating measured current with the enzyme reaction); and

d) means for correlating the rate of reduction of the enzymatically-liberated hydrogen peroxide by the working electrode with the concentration of the analyte in an aqueous fluid

sample (implied by paragraph [0018] of the "Detailed Description, " which teaches that the hydrogen peroxide generation is proportional to the glucose concentration).

Addressing claims 3 and 11, at least rhodium is taught (paragraph [0018] of the "Detailed Description").

Addressing claim 4, no membrane is shown in the embodiments in the figures ("Description of the Drawings").

Addressing claim 5, in one embodiment a potential of –0.2 V is used (paragraph [0018] of the "Detailed Description").

Addressing claim 6, Tadahisa teaches a method for direct electrochemical measurement of enzymatically liberated hydrogen peroxide formed incident to the biocatalytic conversion of an analyte of interest (paragraph [0018] of the "Detailed Description"), wherein the analyte is (a) initially exposed to an oxidase specific for biocatalytic conversion of the analyte into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description"), and (b) the hydrogen peroxide is reduced, under electrochemical conditions, so as to generate an electrical signal indicative of the presence and/or concentration of the analyte in the sample (paragraph [0018] of the "Detailed Description"), wherein the improvement comprises

a) providing a biosensor assembly comprising an electrode array having a working electrode (25) and a counter electrode (24), the working electrode having an effective amount of enzymatically active oxidase specific for biocatalytic conversion of an analyte of interest into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description"), and a metal doped carbon composition specific for catalytic reduction of enzymatically-liberated hydrogen peroxide (paragraphs [0006] and [0018] of the "Detailed Description");

b) applying an aqueous test sample suspected of containing an analyte of interest to the electrode array of the biosensor, under biocatalytic conditions (paragraph [0018] of the "Detailed Description");

b) applying an electrical potential to the electrodes, under catalytic reduction conditions (paragraph [0018] of the "Detailed Description". Also note the embodiment in paragraph [0018] of the "Detailed Description" in which 0.7 V is used);

c) monitoring an electrical signal generated by the catalytic reduction of enzymatically-liberated hydrogen peroxide over a period of time until constant (implied in paragraph [0018] of the "Detailed Description " by the wait of 5 seconds after applying the potential before making the measurement); and

d) correlating the constant electrical signal with a concentration of the analyte in the aqueous sample (implied by paragraph [0018] of the "Detailed Description, " which teaches that the hydrogen peroxide generation is proportional to the glucose concentration).

Addressing claim 7, Tadahisa teaches a biosensor assembly for the selective determination of an analyte in an aqueous sample by direct electrochemical measurement of enzymatically liberated hydrogen peroxide, the improvement comprising

a working electrode (25) and a counter electrode (24), the working electrode comprising an electrically conductive deposit having an effective amount of enzymatically active oxidase specific for biocatalytic conversion of an analyte of interest into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description "), and a metal doped carbon composition specific for catalytic reduction of enzymatically-liberated hydrogen peroxide (paragraphs [0006] and [0018] of the "Detailed Description "), the working electrode being devoid of a perm-selective membrane (no membrane is shown in the embodiments in the figures. See the "Description of the Drawings") and yet effective for selective determination of enzymatically-liberated hydrogen peroxide over a potential range of about +0.10 V to about – 0.20 V in an aqueous sample (paragraph [0018] of the "Detailed Description ").

Addressing claim 8, drawing 5 shows an embodiment in which the first insulating substrate (22) is longer the second insulating layer (23). Note the aperture (27A) corresponding to an analysis or test site.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JPO computer translation of Tadahisa (JP 09-264870), hereafter "Tadahisa," in view of Henning et al. (US 5,755,953), hereafter "Henning," and pages 94-95 of the *Kirk-Othmer Encyclopedia of Chemical Technology*, 4th ed., vol.9, John-Wiley & Sons, 1994, hereafter "Kirk-Othmer."

Addressing Claim 2, Tadahisa teaches a system for direct electrochemical measurement of enzymatically liberated hydrogen peroxide formed incident to the biocatalytic conversion of an analyte of interest (paragraph [0018] of the "Detailed Description"), wherein the analyte is (a) initially exposed to an oxidase specific for biocatalytic conversion of the analyte into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description"), and (b) the hydrogen peroxide is reduced, under electrochemical conditions, so as to generate an electrical signal indicative of the presence and/or concentration of the analyte in the sample (paragraph [0018] of the "Detailed Description"), wherein the improvement comprises

a) providing a biosensor assembly comprising a working electrode (25) and a counter electrode (24), the working electrode having an effective amount of enzymatically active oxidase specific for biocatalytic conversion of an analyte of interest into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description"), and a metal doped carbon composition specific for catalytic reduction of enzymatically-liberated hydrogen peroxide (paragraphs [0006] and [0018] of the "Detailed Description");

b) means for applying an electrical potential to the electrodes, wherein the potential is within a range of from about +0.4 V of about –0.3 (paragraph [0018] of the "Detailed

Description". Also note the embodiment in paragraph [0018] of the "Detailed Description" in which 0.7 V is used);

c) means for monitoring, under electrochemical conditions, the rate of catalytic reduction of enzymatically –liberated hydrogen peroxide by the working electrode (implied by paragraph [0018] of the "Detailed Description, " which teaches correlating measured current with the enzyme reaction); and

d) means for correlating the rate of reduction of the enzymatically-liberated hydrogen peroxide by the working electrode with the concentration of the analyte in an aqueous fluid sample (implied by paragraph [0018] of the "Detailed Description, " which teaches that the hydrogen peroxide generation is proportional to the glucose concentration).

Tadahisa does not mention providing a third electrode (although it should be noted that in the description of the prior art providing a third electrode is disclosed (drawing 7)).

Henning teaches a biosensor comprising a working electrode, a counter electrode, a reference electrode, and a reaction layer containing peroxidase and platinum or ruthenium containing carbon particles (abstract; Figure 1; and col. 4, ln. 45 – col. 5, ln. 14). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide separate counter and reference electrodes as taught by Henning in the invention of Tadahisa because as was known in the art at the time of the invention this will improve the accuracy of the biosensor since the reference electrode will be stabilized by having the bulk of the current flow go through the counter electrode instead of the reference electrode (Kirk-Othmer).

Addressing Cliam 10, Tadahisa teaches a biosensor assembly for the selective determination of an analyte in an aqueous sample by direct electrochemical measurement of enzymatically liberated hydrogen peroxide, the improvement comprising

a working electrode (25) and a counter electrode (24), the working electrode comprising an electrically conductive deposit having an effective amount of enzymatically active oxidase specific for biocatalytic conversion of an analyte of interest into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description "), and a metal doped carbon composition specific for catalytic reduction of enzymatically-liberated hydrogen peroxide (paragraphs [0006] and [0018] of the "Detailed Description "), the working electrode being devoid of a perm-selective membrane (no membrane is shown in the embodiments in the figures. See the "Description of the Drawings") and yet effective for selective determination of enzymatically-liberated hydrogen peroxide over a potential range of about +0.10 V to about – 0.20 V in an aqueous sample (paragraph [0018] of the "Detailed Description "). Drawing 5 shows an embodiment in which the first insulating substrate (22) is longer the second insulating layer (23). Note the aperture (27A) corresponding to an analysis or test site.

Tadahisa does not mention providing a third electrode (although it should be noted that in the description of the prior art providing a third electrode is disclosed (drawing 7)).

Henning teaches a biosensor comprising a working electrode, a counter electrode, a reference electrode, and a reaction layer containing peroxidase and platinum or ruthenium containing carbon particles (abstract; Figure 1; and col. 4, ln. 45 – col. 5, ln. 14). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide separate counter and reference electrodes as taught by Henning in the invention of Tadahisa

because as was known in the art at the time of the invention this will improve the accuracy of the biosensor since the reference electrode will be stabilized by having the bulk of the current flow go through the counter electrode instead of the reference electrode (Kirk-Othmer).

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over JPO computer translation of Tadahisa (JP 09-264870), hereafter "Tadahisa," in view of Maley et al. (US 5,779,028), hereafter "Maley."

Tadahisa teaches a biosensor assembly for the selective determination of an analyte in an aqueous sample by direct electrochemical measurement of enzymatically liberated hydrogen peroxide, the improvement comprising

a working electrode (25) and a counter electrode (24), the working electrode comprising an electrically conductive deposit having an effective amount of enzymatically active oxidase specific for biocatalytic conversion of an analyte of interest into one or more by-products, including hydrogen peroxide (paragraph [0018] of the "Detailed Description "), and a metal doped carbon composition specific for catalytic reduction of enzymatically-liberated hydrogen peroxide (paragraphs [0006] and [0018] of the "Detailed Description "), the working electrode being devoid of a perm-selective membrane (no membrane is shown in the embodiments in the figures. See the "Description of the Drawings") and yet effective for selective determination of enzymatically-liberated hydrogen peroxide over a potential range of about +0.10 V to about –0.20 V in an aqueous sample (paragraph [0018] of the "Detailed Description "). Drawing 5

shows an embodiment in which the first insulating substrate (22) is longer the second insulating layer (23). Note the aperture (27A) corresponding to an analysis or test site.

Tadahisa does not mention providing a filter member

Maley teaches a biosensor comprising a working electrode; a counter electrode; a reference electrode, a reaction layer containing peroxidase platinum or another platinum group metal and carbon particles; and a filter member (membrane) (abstract; col. 13, ll. 53-64; col. 14, ll. 12-65; and col. 5, ll. 60-63; and col. 17, ll. 24-56). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a filter membrane as taught by Maley in the invention of Tadahisa because as taught by Maley the filter will contaminate in the sample from adversely affecting the accuracy of the measurement (col. 17, ll. 24-27 and col. 23, ll. 44-49).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
May 1, 2004